UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, ILLINOIS 60604

SUBJECT:	CLEAN AIR ACT INSPECTION REPORT Fresenius Kabi USA, Melrose Park, Illinois
FROM:	Karina Kuc, Environmental Engineer AECAB (IL/IN)
THRU:	Nathan Frank, Section Supervisor AECAB (IL/IN)
TO:	File

BASIC INFORMATION

Facility Name: Fresenius Kabi USA

Facility Location: 2020 N Ruby Street, Melrose Park, Illinois 60160

Date of Inspection: 7/20/2022

EPA Inspector(s):
1. Karina Kuc, Environmental Engineer
2. Tess Russell, Environmental Engineer

Other Attendees:
1. Brendan Martin, Maintenance Manager, Fresenius Kabi USA

Contact Email Address: Mario.Varela@fresenius-kabi.com and Karol.Sole@fresenius-kabi.com

Purpose of Inspection: to assess compliance with the facility's construction permit and the State Implementation Plan (SIP)

Facility Type: pharmaceutical manufacturer

Arrival Time: 1:45 PM

Departure Time: 4:05 PM

Inspection Type:

☒ Unannounced Inspection
☐ Announced Inspection

OPENING CONFERENCE

☒ Presented Credentials
☒ Stated authority and purpose of inspection
☐ Provided Small Business Resource Information Sheet
☒ Small Business Resource Information Sheet not provided. Reason: Not a small business
☒ Provided CBI warning to facility

The following information was obtained verbally from Brendan Martin unless otherwise noted.

Process Description:

The facility makes various injectables such as pain medication, vitamins and antiviral medication. Raw materials include city water, active pharmaceutical ingredients (APIs), and glass vials. City water is purified by filtration and distillation to create water for injection (WFI). APIs are shipped in the form of powders, oils and solids. Empty glass vials get cleaned by depyrogenation by baking in one of four ovens. Component sterilizers utilizing only steam are used to sterilize other various parts. The WFI and APIs are mixed in tanks according to formulations. The facility makes over 250 different formulations. Hazardous or toxic APIs, most often in powder form, are charged to the tanks under a dust collector. Certain formulations call for APIs to be dissolved in solvents (usually ethyl alchol) before being mixed with WFI, or for the temperature of the mixing tanks to be raised or lowered. Some formulations are freeze dried to extend shelf life. The mixture is then pumped through hoses to the first floor where the glass vials are filled, capped, and packaged, then shipped as the final product.

Staff Interview:

Tanks go through a validation process to ensure the integrity of the final product. The facility has a total of about 20 to 30 mobile and stationary tanks which range in size from about 400 to 3000 liters. The mixing tanks utilize a sterile filter to maintain ambient pressure and are vented into the building. The tanks are equipped with rupture discs. Some components have a nitrogen over-blanket. The facility has three dust collectors: two for hazardous materials and one for non-hazardous materials.

The facility uses solvents such as isopropyl alcohol for surface sterilization. Wastewater is pretreated before being sent for disposal. The facility recently built and expanded into a new building adjacent to its old building. The expansion included two new boilers which will replace the old boilers in the original building. Hazardous waste is picked up and incinerated at Veolia. The quality control lab runs whenever production is running.

TOUR INFORMATION

EPA Tour of the Facility: Yes

Data Collected and Observations:
EPA observed the pressure drop reading on the non-hazardous dust collector to be jumping around, reading -0.2 to 0.4" water column. Brendan Martin stated that the dust collector may have been in a cleaning cycle. Documents obtained after the inspection state the proper range for the dust collector is less than or equal to 1.5" water column.

Photos and/or Videos: were taken during the inspection.
Field Measurements: were not taken during this inspection.

CLOSING CONFERENCE

☒ Provided U.S. EPA point of contact to the facility

Requested documents:

- SDSs for top 10 substances used in formulations
- Annual emissions tracking spreadsheet with throughputs and emission factors for 2020 and 2021
- Formulation solvent usage records and emissions for 2020 and 2021 (may be included in annual emissions spreadsheet)
- Cleaning solvent usage records and emissions for 2020 and 2021 (may be included in annual emissions spreadsheet)
    - If not already included, provide the VOM content of each as-used cleaning solution in 2020 and 2021;
    - Or provide the VOM composite partial vapor pressure of each as-used cleaning solution.
- SOP for cleaning tanks
- Explanation of if/how/which tanks are vented during formulation heating or mixing
- Explanation of any monitoring of dust collectors (including, but not limited to, frequency of monitoring and/or maintenance) and if/how you account for them in the emissions tracking spreadsheet
- Explanation of which solvents are used in formulations and how often

Concern: EPA noted that the observed pressure readout on the dust collector may be an issue if the unit was not in a cleaning cycle.

DIGITAL SIGNATURES

Report Author: KARINA KUC Digitally signed by KARINA KUC Date: 2022.08.31 13:44:54 -05'00'

Section Supervisor: Frank, Nathan Digitally signed by Frank, Nathan Date: 2022.09.08 16:27:33 -05'00'

APPENDICES AND ATTACHMENTS

Appendix A – Digital Image Log

Facility Name: Fresenius Kabi
Facility Location: 2020 N Ruby Street, Melrose Park, Illinois 60160
Date of Inspection: July 20, 2022

APPENDIX A: DIGITAL IMAGE LOG

1. **Inspector Name:** Karina Kuc	2. **Archival Record Location:** Electronic Record Center

Image Number	File Name	Date and Time (incl. Time zone and DST)	Description of Image
1	P7200033.JPG	7/20/2022 2:44 PM	Pressure drop readout from non-hazardous dust collector